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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FOX ROTHSCHILD LLP			KANTAMneni, SHOBHA	
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PHILADELPHIA, PA 19107			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/719,588	Applicant(s) ANSMANN ET AL.
	Examiner Shobha Kantamneni	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 September 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-5 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) NONE is/are allowed.
- 6) Claim(s) 2-5, 14-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/1449)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

This office action is in response to Applicant's response filed on 09/23/2008.

The rejection of claims 16-19 under 35 U.S.C. 112, first paragraph, is MAINTAINED.

See under response to arguments.

Applicant's arguments have been considered, but not found persuasive. The rejection of claims 2-5, and 14-21 under 35 U.S.C. 103(a) as being unpatentable over Garland et al. (Journal of the American Chemical Society, Sept, 1925, pages 2333-2340, PTO-1449), and in view of Luisi (WO 8900077, PTO-1449) is MAINTAINED. See under response to arguments.

Claims 2-5, 14-21 are examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment with respect to claims 16-17 filed on 09/17/2007, and new claims 18-19 filed on 04/08/2008 has been fully considered but is deemed to insert new matter into the claims, since the specification as originally filed does not provide

support for the limitation, "wherein the amount of the compound of formula (III) or formula (IV) present in the pharmaceutical composition is from 0.1 % to 50 % by weight", and "wherein the amount of the compound of formula (III) or formula (IV) present in the pharmaceutical composition is from 0.1 % to 30 % by weight". The original specification merely discloses that the dicyclic compounds are suitable for use in pharmaceutical preparations. See page 3, lines 19-20; page 4, lines 18-20. Accordingly, the claimed subject matter has not been described in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed were actually in possession of such as pharmaceutical composition having the particular amounts, and thus the claim fails to meet the written description.

Response to Arguments

Applicant's arguments have been considered, but not found persuasive. It is pointed out that contrary to applicant's remarks that "Applicant's hereby cancel claims 16-19", applicant's claim amendment did not cancel claims 16-19. Hence, the rejection is MAINTAINED.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-5, and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garland et al. (Journal of the American Chemical Society, Sept, 1925, pages 2333-2340, PTO-1449), and in view of Luisi (WO 8900077, PTO-1449).

Garland et al. disclose composition comprising 1-methyl-2-cyclohexyl-cyclohexane, and 1-ethyl-2-cyclohexyl-cyclohexane.

Garland et al. does not teach the particular compound of formula (III), or formula (IV) as in claims 2-3, and 14-15, and the employment of the compound of formula (III) or formula (IV) in a cosmetic and pharmaceutical composition.

Garland et al. do not teach the amounts of bicyclohexyl compounds in the compositions therein as 0. 1 % to 50 % by weight.

Luisi teaches that bicyclohexyl compounds are employed in pharmaceutical preparations as solvents. See page 9; page 17, claim 5.

It would have been obvious to a person of ordinary skill in the art at the time of the invention to the particular instant compounds of formula (III) or (IV) in the prior art composition of Luisi because 1) Garland et al. teaches that alkyl substituted bicyclohexyl compounds are known in the art, and 2) Luisi teaches that cycloalkanes which include bicyclohexyl compounds, and cyclopentane are known to be useful as solvents in pharmaceutical preparation.

Therefore, one of ordinary skill in the art would have been reasonably expected that the instant particular alkyl substituted bicyclohexyl or bicyclopentyl compounds of formula (III), or (IV), would have same or substantially similar usefulness as solvents in

pharmaceutical preparation such as bicyclohexyl compounds taught by Luisi, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g., Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214, and if the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species. In fact, similar properties may normally be presumed when compounds are very close in structure. Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904, as noted in MPEP 2144.

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of the bicyclohexyl compounds employed in the composition of Garland et al. to obtain a pharmaceutical composition, a cosmetic composition, since Luisi teaches that bicyclohexyl compounds are known to be used as solvents in pharmaceutical composition.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of bicyclohexyl compounds employed in the compositions, since the optimization of effective amounts of known agents, is considered well in the competence level of an ordinary skilled artisan in cosmetic and pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments have been considered, but not found persuasive.

Applicant argues that "the selective picking and choosing of elements from references so far removed from one another in time strongly indicates impermissible hindsight reconstruction". These arguments have been considered, but not found persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argues that "it is well known in the chemical arts that multiple alkyl substitution of an alkyl residue, particularly geminal-dialkyl substitution to form quaternary carbon centers, imparts physico-chemical properties, such as boiling point, melting point, and solubility characteristics, that are neither additive nor predictable." These arguments have been considered, but not found persuasive, since applicant

merely presents statements, or speculations or opinions but fails to set forth any factual evidences.

Luisi teaches that cycloalkanes which include bicyclohexyl compounds, and cyclopentane are known to be useful as solvents in pharmaceutical preparation. Thus, considering Luisi reference as a whole one would have been motivated to employ bicyclohexyl compounds, and cyclopentyl compounds as solvents in pharmaceutical preparations. Further, according to Garland et al., alkyl substituted bicyclohexyl compounds are known in the art. Accordingly, it would have been obvious to a person of ordinary skill in the art at the time of the invention to the particular instant alkyl substituted bicyclohexyl compounds of formula (III) or (IV) in the prior art composition of Luisi because 1) Garland et al. teaches that alkyl substituted bicyclohexyl compounds are known in the art, and 2) Luisi teaches that cycloalkanes which include bicyclohexyl compounds, and cyclopentane are known to be useful as solvents in pharmaceutical preparation.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D

Patent Examiner

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/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617

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